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10/783,362	02/20/2004	Shiping Wang	GL-6188	2424

EXAMINER	
AHMED, HASAN SYED	

ART UNIT	PAPER NUMBER
1615	

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ALLEGIANCE CORPORATION  
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/783,362

Applicant(s)

WANG ET AL.

Examiner

Hasan S. Ahmed

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-26 and 35-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Receipt is acknowledged of applicants' amendment and response, which were filed on 20 September 2007.

\* \* \* \* \*

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-34 remain rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,133,090 ("Modak").

Modak recites an antimicrobial elastomeric article (see col. 2, lines 26-29). The disclosed article is the instant article, as claimed:

- the antimicrobial of instant claim 27 (see col. 2, line 26);
- the elastomeric material of instant claim 27 (see col. 2, line 30);
- the chlorhexidine salt of instant claim 27 (see col. 2, line 50);
- the quaternary ammonium halide of instant claim 27 (see col. 2, line 61);
- the glove of instant claim 28 (see col. 2, line 26);
- the chlorhexidine salt and quaternary ammonium halide of instant claim 29 (see col. 2, lines 50 and 61); and
- the chlorhexidine salt and benzalkonium chloride of instant claim 34 quaternary ammonium halide of instant claim 27 (see col. 2, lines 50 and 61).

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Modak discloses a glove essentially free of starch and powder, as recited in instant claim 32.

The processes of extending the antimicrobial activity of the elastomeric article recited in claims 27, 30, 31 and 33 are not essential to a determination of patentability of the article disclosed in the claim. The patentability of product-by-process claims is based on the product itself. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

\* \* \* \* \*

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Modak in view of U.S. Application No. 2002/0152538 ("McDevitt").

Modak teaches an antimicrobial elastomeric article (see above).

The Modak reference differs from the instant application in that it does not teach a process of extending antimicrobial activity.

McDevitt teaches an elastomeric glove (see paragraph 0054). The disclosed glove is comprised of:

- the antimicrobial agent of instant claim 27 (see paragraph 0030);
- the packaging of instant claim 27 (see paragraph 0189); and
- the moisture-resistant barrier container (e.g. film foil laminate) of instant claim 33 (see paragraph 0189).

McDevitt explains that packaging the gloves is beneficial, "...in order to preserve any additives applied to the finger glove or otherwise to maintain the finger glove in a sterile environment." See paragraph 0189.

The reference is silent with respect to the time recited in instant claim 30 and the antimicrobial activity recited in instant claim 31. Applicants' composition, as claimed, is the same as the prior art. As, claimed, applicants' article contains the same components in the same configuration as the prior art. Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a process of extending antimicrobial activity of an elastomeric article by using a moisture-resistant barrier container, as taught by Modak

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in view of McDevitt. One of ordinary skill in the art at the time the invention was made would have been motivated to use such a process because it leads to preservation of additives (such as antimicrobial agent), as explained by McDevitt.

\* \* \* \* \*

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-28 of copending Application No. 11/271,666 ('666). Although the conflicting claims are not identical, they are not patentably distinct from each other because '666 claims an elastomeric article comprising chlorhexidine and benzalkonium chloride (claim 13).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

\* \* \* \* \*

### ***Response to Arguments***

Applicants' arguments filed 20 September 2007 have been fully considered but they are not persuasive.

#### ***35 USC 102***

Applicants argue that the 35 USC 102 rejection is obviated by amending the independent claim to recite, "A packaged antimicrobial elastomeric article..." See remarks, page 8.

Initially, it should be noted that applicants admit that independent claim 27 is a product-by-process claim (see remarks, page 8, last paragraph). Thus, patentability turns on the product itself, i.e. the elastomeric article, not the process of packaging.

Furthermore, the recitation "packaged" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Here, the structural limitations stand alone, and the process steps are not given patentable weight.

\*

*35 USC 103*

1. Applicants argue that the 35 USC 103 rejection is obviated because the prior art teaches additives in addition to the materials instantly claimed. See remarks, pages 8-9.

The transitional term "comprising"; which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising, the terms containing and mixture are open-ended."). See MPEP 2111.03. Thus, examiner respectfully submits that the prior art reads on the instant application as claimed.

2. Applicants argue that, "...McDevitt neither teaches nor suggests a packaging that is a means for reducing the relative humidity to less than ambient relative humidity." See remarks, page 10.

As stated above, independent claim 27 is a product-by-process claim. Thus, patentability turns on the product itself, i.e. the elastomeric article, not the process of packaging.

Furthermore, the phrase "means for reducing the relative humidity to less than ambient relative humidity" is very broad in scope.

The term "ambient" is not defined in the instant specification. Merriam-Webster dictionary defines ambient as "an encompassing atmosphere." See entry, attached. Thus, when the claim is read in light of its broadest reasonable interpretation, McDevitt



is on point. McDevitt specifically discloses "... various sealed packaging in order to preserve any additives applied to the finger glove or...to maintain the finger glove in a sterile environment." See paragraph 0189. The packaging materials may include packaging that is completely impermeable or differentially permeable (see paragraph 0189).

Thus, in accordance with the teachings of McDevitt, the gloves may be packaged in a low humidity environment to enhance sterility. That *de minimus* water vapor content will not change when the package is introduced into an environment with high "ambient" humidity if the gloves are packaged in an impermeable material. Such a circumstance reads on the instant claims as currently drafted.

3. Applicants argue that, "...none of the 35 working examples disclosed by McDevitt teach a packaging for a finger glove with an antimicrobial coating. Indeed, none of the 35 working examples disclosed by McDevitt teach a finger glove with an antimicrobial coating at all." See remarks, page 10.

Examiner respectfully submits that working examples in a reference are not required in order to establish a *prima facie* case of obviousness. "A reference can be used for all it realistically teaches and is not limited to the disclosures in its specific examples." See *In re Van Marter et al.* 144 USPQ 421; *In re Wndmer et al.* 147 USPQ 518, 523; and *In re Chapman et al.* 148 USPQ 711. McDevitt teaches both a packaging and an antimicrobial (see substantive rejection, above).

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4. Applicants argue that, "...McDevitt does not teach, suggest, or motivate on of ordinary skill in the art to seek a means of reducing relative humidity as recited in instant claim 27." See remarks, page 11.

Examiner respectfully submits that applicants have not provided a specific means of reducing relative humidity in claim 27. They merely recite a generic concept of broad scope. As explained above, the McDevitt reference reads on that concept, as it is currently claimed.

5. Applicants argue that McDevitt teaches away from the instant application because, "[a] packaging that is not completely permeable is unable to maintain the relative humidity in the vicinity of the elastomeric article less than ambient relative humidity. See remarks, page 11.

Examiner respectfully submits that this argument contradicts the instant specification, which discloses a packaging that is "not completely permeable," i.e. a water-vapor-impermeable barrier (see paragraph 0037).

6. Applicants argue that McDevitt teaches away from the instant application because, "...a packaging that is completely impermeable necessarily maintains the relative humidity in the vicinity of the elastomeric article at exactly ambient humidity." See remarks, page 11.

Examiner respectfully submits that the McDevitt discloses (in-part) the same materials for packaging as the instant application, i.e. metallized films and foil laminates (paragraph 0189 of McDevitt, paragraph 0035 of the instant application).

7. Applicants argue that dependent claim 33 is patentable because McDevitt does not teach a dessicant. See remarks, page 11.

Examiner respectfully submits that the dessicant in claim 33 is optional because of alternative language. McDevitt reads on the alternative to a dessicant listed in claim 33, i.e. a moisture-resistant barrier container (see substantive rejection, above).

\* \* \* \* \*

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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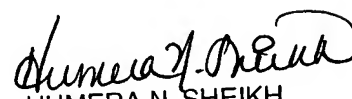
***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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HUMERA N SHEIKH  
PRIMARY EXAMINER